

ARGUMENT

Claims 11, 14, 28-49, 51, 53-56 and 58-60 are pending in the application, of which Claims 28-49, 51 and 53-56 are withdrawn from consideration. Claim 11 stands rejected as being anticipated under 35 U.S.C. § 102(e) by Fire et al. U.S. PN 6,506,559 ("Fire"). Claims 11, 14 and 58-60 stand rejected as obvious under 35 U.S.C. § 103(a) over Fire taken with international patent application No. WO 94/11494 ("the '494 application").

Applicants amend Claim 11. This amendment restores the language of that claim prior to the March 10, 2004, amendment to that claim with respect to recitation of nucleic acid. Applicants respectfully request Examiner allows Claim 11 and its dependents in view of the following arguments.

Rejection: Anticipation

Examiner rejected Claim 11 as anticipated under 35 U.S.C. § 102(e) by Fire for reasons given at pages 6-7 of the November 10, 2003 Office Action, because Fire teach methods of inhibiting expression of a target gene within a cell comprising identifying and delivering inhibitory RNA, which can be delivered in the form of RNA or DNA (citing columns 12-13) and which is homologous to portions of the endogenous gene that mutes at the level of post-transcription (citing column 6). In the June 1, 2004 Office Action, Examiner points to the paragraph bridging column 8-9 as teaching regulatory regions to be included as part of the introduced transgene or expression construct to direct transcription.

Fire's method fails to anticipate because it does not disclose the process of the invention recited in the rejected claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. V. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in ... claim." Richardson v. Suzuki Motor, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). See MPEP 2131.

Fire fails to teach a process to mute expression of a target gene in a population of animal cells by delivering a double-stranded ("ds") DNA to the population of cells, as was required by Claim 11 (prior to the present amendment). At columns 12-13, Fire states

"duplex RNA can be produced in vivo or in vitro transcription from an expression construct used to produce [a gene] library. The construct can be replicated as individual clones of the library and transcribed to produce the RNA; each clone can *then* be fed to, or injected into, the cell/organism containing the target gene."

(Emphasis added.) Fire expressly require first producing RNA outside the target cell followed by addition of the RNA transcripts to the cell. The bridging paragraph between columns 8-9 states only that "RNA may be synthesized either in vivo or in vitro [including from] a transgene in vivo or an expression construct." Fire fail to demonstrate that the transgene or expression construct they refer to is introduced to the cell containing the target gene. To the contrary, in the next paragraph, Fire extensively describe how RNA is delivered to the target cell (see column 9, lines 26-64); Fire never mention delivering dsDNA for RNA transcription in the same cell as the target gene in their patent disclosure. Applicants respectfully submit that Examiner's statement that Fire teach delivery of dsDNA is inapposite to Fire's express disclosure: the sections relied upon by Examiner shows RNA produced in cells other than a cell with the target gene.

Accordingly, the process recited in Claim 11 of the instant application is not anticipated by Fire since that reference does not teach a process to mute expression of a target gene in a population of animal cells by delivering a dsDNA to the population of cells.

Notwithstanding Fire's failure to disclose the invention recited in Claim 11, Applicants now submit a Declaration under 37 CFR 1.131 as inventors of the subject matter of the rejected claims. Applicants here petition under 37 CFR § 1.91 for entry of the Declaration and attached notebook pages as part of the record of the instant patent application. Entry of this exhibit is respectfully requested because it is necessary to demonstrate patentability of the invention recited in the rejected claims. This petition is accompanied by payment of the petition fee pursuant to 37 CFR § 1.17(i).

In their Declaration, Applicants aver that based on notebook records, copies of which are attached to the Declaration, the subject matter of the rejected claims of the patent application was reduced to practice before December 23, 1997, the effective filing date of Fire (MPEP 706.02). The Declaration may be used because the patent date of Fire, a U.S. Patent, is less than 1 year prior to Applicants' effective filing date, and it does not claim the same patentable invention as recited in the rejected claims. (See MPEP 715.) By factually demonstrating priority of invention over Fire, Applicants effectively remove it as a § 102(e) prior art reference.

Rejection: Obviousness

Examiner rejected Claim 11, 14 and 58-60 as obvious under over Fire and the '494 application for reasons given at pages 8-10 of Examiner's 11/10/03 Office Action. Examiner there cited Fire for the reasons discussed *supra* in connection with the anticipation rejection. Examiner cited the '494 application for teaching a method for inhibiting the expression of human or mouse procollagen gene in rodent cells using antisense sequences (citing pages 6-7 and 17), which can be used to treat diseases related to mutant procollagen genes (citing pages 4-6).

As discussed *supra* in connection with the anticipation rejection, Fire fail to teach a step of delivering a ds DNA composition into the population of cells comprising the target gene, as was required by Claim 11 (prior to the present amendment). Fire similarly fail to disclose the invention of the remaining rejected claims, which are dependent from Claim 11. The deficiencies of the rejected claims are not cured by the disclosure of the '494 application. Pages 4-7 and 17 describe single-stranded oligonucleotides designed to target collagen genes, particularly oligonucleotides that are complementary to the sequence of human and mouse COL1A1 genes. The '494 application fails to disclose methods of delivering a dsDNA (or dsRNA) composition into a population of cells with a target gene.

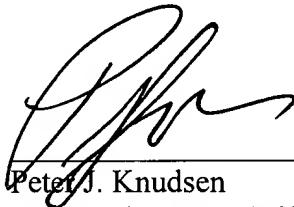
Further to Fire's failure to disclose the invention recited in Claim 11, Applicants here submit a Rule 131 Declaration in which they aver that based on their notebook records, the subject matter of all of the rejected claims of the patent application was

reduced to practice prior to December 23, 1997, the effective filing date of Fire. The Declaration applies equally Claim 11 and all rejected claims dependent from Claim 11.

Accordingly, the process disclosed in the rejected claims of the instant application are nonobvious over Fire and the '494 application alone or combined since neither reference teaches the process recited in independent Claim 11, including a process to mute expression of a target gene in a population of animal cells by delivering a double-stranded nucleotide to the population of cells. Moreover, the Fire patent is not prior art to the invention of the rejected claims.

Applicant hereby requests further examination and reconsideration of the application in view of the foregoing amendments. Applicant believes that after these amendments all of the claims are in condition for allowance.

Respectfully submitted,



Peter J. Knudsen
Registration No. 40,682

Peter J. Knudsen
Knudsen, Attorney at Law, LLC
Customer No. 46,167

13710 Riviera Pl, NE
Seattle, WA 98125
T, office: 206-367-0259
F: 206-367-5083
T, mobile: 206-353-0544
knudsen.llc@comcast.net